Permission given for clinical trial (r-DNA based Drug Product) (2013)

S.NO.	File No.	Name of Firm	Name of Drug Product	Title of The Study	Date of Approval
1	4-73/Reliance/10-BD	Reliance life science pvt. Ltd	Reteplase (RTPR-004)	"A Prospective multicentric single arm, clinical study to evaluate effocacu amd saferu pf R-TPR-004 in patients undergoing treatment for acute ischemic stroke vide protocol No. RLS/TP/2010/03, version 2.0 dated 03/10/2012"	4-Mar-13
2	4-126/CADILA/12-BD	Cadila Healthcare Ltd	Rituximab	"A randomized controlled study to evaluate pharmacokinetic, pharmacodynamics (efficacy) and safety of Rituximab (Zydus) and Rituximab (Roche) in patients with Rheumatoid Arthritis" vide Protocol No. RIT.11.001.01, version 1.1 dated 06/11/2012	21-Mar-13
3	4-164/Quintiles/12-BD	Quintiles Phase One Clinical Trials pvt. Ltd.	egfilgrastim	"Pharmacokinetic and Pharmacodynamic Bioequivalence of Single Dose Zydus Pegfilgrastim to Neulasta Pegfilgrastim from US and EU source" vide protocol No. QHYD - 0001, Version 1.0 dated 31/05/2012	16-Apr-13
4	4-154/Mabpharm/12-BD	Mabpharma Pvt Ltd	Pegfilgrastim	"An Open-label, multi-centric, parallel group, comparative, randomized study to compare the safety and efficacy of Trastuzumab power for soluction for infusion manufactured by Mabpharm Pvt. Ltd.,withHerception of Roche Ltd., UK in patients with HER2 overexpressing metastatic breast cancer" vide Protocol No. MAB/01/2011,version 03, dated 25/06/2013	17-Apr-13
5	4-112/RELIANCE/11-BD	Reliance Life Science Pvt. Ltd	Pegfilgrastim	A randomized, balanced, open-label, two-treatment, two sequence, two-period, single subcutaneous dose, crossover stidy to compare the	8-May-13

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				pharmacokinetics/pharmacodynamics (PK/PD) of test R-TPR-029 (Pegfilgrastim 6mg/0.6ml) of Reliance Life Sciences Pvt. Ltd., India with reference Neulasta (Neulastim) Pegfilgrastim 6mg/0.6ml of Amgen Ltd." vide Protocol No. RC/0812/039, version 3.0 dated 20/12/ 2012-reg.	
6	4-175/Hetero/12-BD	Hetro	Rituximab	"A randomized, multi-dose, multicente, comparative parallel study to evaluate the efficacy, safety and pharmacokinetic charactteristics of Intravenous infusion of Rituximab (Hetero) and Reference Medicial Product (Rituximab, Roche) In indian Patients of Non-Hodgkin's Lymphoma (HERILY study)"vide Protocol No. HCR/III/Ritux/06/2012, Version 1.1 dated01/11/2012	14-may 13
7	4-135/symmetrix /12-BD	M/s Symmetrix Biotech Private Limited	smrx-11	**"**Efficacy and safety of bolus injection of a novel thrombolytic agent (smrx-11) in patients with acute st-segment elevation myocardial infarction STEMI A phase II open label dose escalation multi centre angiographic trial" vide protocol no .13-vin-287 (cssksmrx-11) version D02, dated 17/07/2013	19-Dec 2013